510(k) Summary

(As required by 21 CFR 807.92(c))

JUN - 1 2007

510(k) Number: K070372

Date Prepared

May 29, 2007

Submitter Information

Submitter's Name:	Vascular Solutions, Inc.
Address:	6464 Sycamore Court Minneapolis, MN 55369
Contact Person:	Julie Tapper Senior Regulatory Affairs Associate Phone 763-656-4228 Fax 763-656-4253

Device Information

Trade Name:	Gopher™ Support Catheter
Common Name:	Percutaneous catheter
Class:	II
Classification Name:	Percutaneous catheter (21 CFR 870.1250, Product Code DQY)

Predicate Devices

Skyway™ Support Catheter (K052258 and K060327), manufactured by Vascular Solutions, Inc.

Tornus Support Catheter (K051772), manufactured by Asahi Intecc Co., Ltd.

Device Description

The Gopher catheter is available in two sizes—2F and 3F. Each catheter assembly has a polymeric outer layer and Nitinol middle layer that extend the length of the catheter. At the distal end, the Nitinol tubing is laser cut and is lined with a PTFE/polyimide inner layer. To provide a radiographic means of locating the tip, the 2F size has a radiopaque markerband near the distal tip and the 3F distal tip is a segment of threaded, radiopaque stainless steel.

Each catheter has printed positioning marks at 95cm and 105cm from the catheter's distal tip, a luer hub and strain relief on the proximal end, and an adjustable torque device near the proximal end. Each Gopher catheter model is compatible with ≥6F guide catheters and ≤0.014″ guidewires and has a working length of approximately 135cm.

The Gopher catheter is provided sterile and intended for a single use.

Intended Use/Indications for Use

The Gopher Support Catheter is intended to be used in conjunction with steerable guidewires in order to access discreet regions of the arterial and/or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic or therapeutic agents.

Summary of Non-clinical Testing

Bench testing was conducted on the Gopher catheter, including the packaging, and included an assessment of the physical properties of the device and its ability to achieve its intended use. The results of the tests confirmed the suitability of the device for its intended use. Each bench test that was conducted is listed, below.

Visual Inspection	Torque Device-to-shaft Interface
Guidewire Interface	Hub-to-proximal shaft Bond Strength
Tortuosity	Distal Shaft Bond Strength
Catheter Kink Resistance	Markerband Visibility (2F)
Guide Catheter Interface	Radiopaque Distal Tip (3F)
Fluid Leak Under Pressure	Packaging—Pouch Visual Appearance after Distribution Testing
Air Leak During Aspiration	Packaging—Product Containment after Distribution Testing
Flow Rate	Packaging—Product Visual Appearance after Distribution Testing
Catheter Integrity After Torquing	Packaging—Label Legibility after Distribution Testing
Torque Strength	

In addition, the biocompatibility of the Gopher catheter was assessed in accordance with ISO 10993, "Biological Evaluation of Medical Devices." The testing confirmed that the materials and processes used in the manufacture of the Gopher catheters are biocompatible. The tests that were conducted are listed, below.

Cytotoxicity	Hemocompatibility, hemolysis
Sensitization	Hemocompatibility, Prothrombin Time
Intracutaneous Reactivity	Hemocompatibility, Lee White Coagulation Test
Acute Systemic Toxicity	Hemocompatibility, *In vitro* Hemocompatibility Assessment
Material Mediated Pyrogen	

Summary of Clinical Testing

Clinical evaluations were not required for this device.

Statement of Equivalence

The Gopher catheter is substantially equivalent to the currently marketed Skyway and Tornus catheters, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods.

Conclusion

The Gopher catheter is substantially equivalent to the currently marketed Skyway and Tornus catheters, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods. Bench tests confirmed the suitability of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 1 2007

Vascular Solutions, Inc.
c/o Ms. Julie Tapper
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, MN 55369

Re: K070372
Gopher™ Support Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II (two)
Product Code: DQY
Dated: May 16, 2007
Received: May 21, 2007

Dear Ms. Tapper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

FOR Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K070372

Device Name:
Gopher™ Support Catheter

Indications for Use:
The Gopher Support Catheter is intended to be used in conjunction with steerable guidewires in order to access discreet regions of the arterial and/or coronary vasculature. It may be used to facilitate placement and exchange of guidewires and other interventional devices and to subselectively infuse/deliver diagnostic or therapeutic agents.

Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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